UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,911	08/09/2006	Susan Elizabeth Bove	PC32145A	8818

26648 7590 09/29/2009

PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

NOTIFICATION DATE	DELIVERY MODE
09/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~ipgsstl@pfizer.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/588,911	**Applicant(s)** BOVE ET AL.	
	Examiner Prema M. Mertz	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2 and 6-12*.
   Claim(s) withdrawn from consideration: *3-5*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Prema Mertz/
Primary Examiner

Continuation of 3. NOTE: The 35 USC 103 rejection of claims 1-2, 6, 9-10 as being unpatentable over Kishimoto et al (US Patent No. 5,888,510) in view of Kaneko et al (2000) is maintained for reasons of record set forth on in the action dated 7/15/09, pages 3-5. Applicants argue that Kishimoto et al. & Kaneko et al. do not disclose a method of treating osteoarthritis by administering an IL- 6 antibody, given the distinct differences between RA and OA, the large number of inflammatory mediators that are elevated, and the significant differences in the levels of IL-6 in RA versus OA one skilled in the art would not have been motivated to treat OA with and IL-6 antibody and the results were not reasonably predicted. Applicants also argue that at best Kaneko et al. relied upon by the Examiner concludes "determination of IL-6 and IL-8 levels is useful for understanding of disease status and making a clinical diagnosis of OA and RA" (page 79, last paragraph) not a preferred target for OA treatment. However, contrary to Applicants arguments, if each of Kishimoto et al and Kaneko et al (2000) disclosed all the limitations of the claims, the instant 35 USC 103 rejection would be a 35 USC 102 rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Kaneko et al teach that significantly higher concentrations of inflammatory cytokine IL-6 levels were found in serum and synovial fluid of patients with osteoarthritis (see abstract, column 1, lines 7-10; Figure 2, page 74; page 78, column 1, last 9 lines, and column 2, first 7 lines) and Kishimoto et al. teach a method for inhibiting synovial cell growth by administering to a patient polyclonal or monoclonal antibodies to IL-6 (see claims 1-4) and also teach a method of treating chronic rheumatoid arthritis by administering to a patient IL-6 antagonists including polyclonal or monoclonal antibodies to the IL-6 receptor (see claims 1-11; Example 2, columns 13-14, column 7, 42-48). Therefore, from the combined teachings of Kishimoto and Kaneko, one of skill in the art would have been motivated to administer IL-6 antibodies for the treatment of OA because Kishimoto teaches the properties of IL-6 antibodies and Kaneko provides the motivation to administer such antibodies. Therefore, the combination of references renders obvious claims 1-2, 6, 9-10.

Claim 7 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Kishimoto et al (US Patent No. 5,888,510) in view of Kaneko et al. (2000) as applied to claims 1-2, 6, 9-10, above, and further in view of Queen et al. (U.S. Patent No. 5,530,101) for the reasons of record set forth in the action dated 7/15/09, pages 5-6. The Queen reference is relied upon in the obviousness rejection because Queen et al., (column 13, lines 5-65) teaches the humanization of monoclonal antibodies.

Claims 11-12, remain rejected under 35 U.S.C. § 103 as being unpatentable over Kishimoto et al (US Patent No. 5,888,510) in view of Kaneko et al. (2000) and Karim et al. (US Patent No. 5,888,510) for the reasons of record set forth in the action dated 7/15/09, pages 6-7. The Karim reference is relied upon in the obviousness rejection because Karim et al teach administration of agents, such as celecoxib or ibuprofen, for fast relief of pain in osteoarthritic patients, is clinically effective for relief of symptoms of pain from osteoarthritis (see column 1, lines 55-65;column 2, lines 33-45).

The final rejection and new grounds of rejection was necessitated by Applicants amendment since Applicants canceled the limitation “corticosteroids” in the amendment filed 5/28/09.